

## **II. Remarks**

### **A. Status of the Claims**

Claims 1-11, 14, 16, 17, and 53-60 are pending, with claims 8 and 9 withdrawn from consideration.

Claims 1-7, 10, 11, 14, 16, 17, and 53-60 are encompassed by the elected invention and the elected species.

### **B. Claim Rejections- 35 U.S.C. § 103**

#### **1. Claims 1-3, 5-7, 10-14, 16, 17, 53-55, 57 and 60**

Claims 1-3, 5-7, 10, 11, 14, 16, 17, 53-57, and 60 were rejected under 35 U.S.C. § 103(a) over U.S. Patent No. 5,639,476 ("Oshlack") in view of U.S. Patent No. 6,136,345 ("Grimmett"), further in view of U.S. Publication 2003/0191147 ("Sherman").

The rejection is respectfully traversed.

Applicants respectfully submit that the cited references, either alone or in combination, do not teach or suggest providing two coatings (i.e., an anionic polymer coating and a hydrophobic material coating over the anionic polymer coating) over a plurality of substrates as recited in present independent claims 1 and 57.

The Examiner contends that "[o]ne of ordinary skill in the art at the time of the invention was made would have been motivated to make such a composition because it provides a stable dissolution of the active agent which is unchanged after exposure to accelerated storage

conditions, as explained by Oshlack.” Office Action, page 4. However, as acknowledged by the Examiner on page 3 of the Office Action, “Oshlack does not teach a coating made of hydrophobic material over the anionic polymer coating” as recited in the present claims. Oshlack therefore does not provide any information on the effect of storage on the dissolution of a formulation comprising the “coating made of hydrophobic material over the anionic polymer coating.” Respectfully, the Examiner’s reliance on the Oshlack to provide the purported motivation is therefore misplaced.

Applicants submit that the structure recited in present claims 1 and 57 is different from the structures suggested by the combination of the cited references. In addition, the structures suggested by the cited references do not include a pharmaceutical formulation comprising a plurality of substrates coated with two coatings as recited in claims 1 and 57.

Applicants further submit that the cited references do not provide any suggestion to use a “coating made of hydrophobic material over the anionic polymer coating” in a pharmaceutical formulation comprising a plurality of substrates as recited in claims 1 and 57. Applicants respectfully note that a coating of hydrophobic material over the anionic coating which is being relied upon by the Examiner on page 3 of the Office Action is the coating in a formulation comprising a single substrate, rather than a plurality of substrates as recited in present independent claims 1 and 57. See, e.g., Grimmert, column 1, lines 39-50. Furthermore, Grimmert actually dissuades from using such a coating in a formulation comprising a plurality of substrates by stating, e.g., that “coating of a single relatively large core ... requires less coating material than is required to coat a large number of smaller granules, and can therefore lead to a relatively low tablet weight.” Column 1, lines 49-54.

The combination of the cited references therefore does not provide a motivation to provide two coatings (i.e., an anionic polymer coating and a hydrophobic material coating over

the anionic polymer coating) on a plurality of substrates, as recited in present claims 1 and 57.

In response to the Examiner's statement on page 6 of the Office Action that "Oshlack was invoked for the teaching of a plurality of coated substrates," Applicants respectfully reiterate that there is nothing in the Oshlack patent, nor any other reference cited by the Examiner, that suggests a formulation comprising a plurality of substrates provided with two coatings as recited in present claims 1 and 57.

For the foregoing reasons, reconsideration and withdrawal of the rejection is respectfully requested.

## **2. Claims 1, 4, 58 and 59**

Claims 1, 4, 58, and 59 were rejected under 35 U.S.C. § 103(a) over U.S. Patent No. 5,639,476 ("Oshlack") in view of U.S. Patent No. 6,136,345 ("Grimmett"), further in view of U.S. Publication 2003/0191147 ("Sherman"), further in view of WO 01/58447 ("Oshlack II").

The rejection is respectfully traversed.

Applicants respectfully submit that none of the cited references, either alone or in combination, provide a reason for providing two coatings (i.e., an anionic polymer coating and a hydrophobic material coating over the anionic polymer coating) over a plurality of substrates as recited in present independent claims 1 and 57, as none of the references show a pharmaceutical formulation comprising a plurality of substrates provided with two coatings as recited in present independent claims 1 and 57, for the reasons given above.

In response to the Examiner's reliance on the Oshlack patent, which "was invoked for the

teaching of a plurality of coated substrates,” Applicants note that there is nothing in the Oshlack patent, nor any other reference cited by the Examiner, that teaches or suggests a formulation comprising a plurality of substrates coated with two coatings as recited in present claims 1 and 57.

As stated above, the coating of hydrophobic material over the anionic coating, which is being relied upon by the Examiner on page 3 of the Office Action, is the coating in a formulation comprising a single substrate, rather than a plurality of substrates as recited in present independent claims 1 and 57. Furthermore, Grimmett actually dissuades from using such a coating in a formulation comprising a plurality of substrates. Column 1, lines 49-54.

For the foregoing reasons, reconsideration and withdrawal of the rejection is respectfully requested.

### III. CONCLUSION

An early and favorable action on the merits is earnestly solicited. The Examiner is respectfully requested to contact the undersigned by telephone in the event that a telephonic interview will advance the prosecution of the present application.

Respectfully submitted,  
DAVIDSON, DAVIDSON & KAPPEL, LLC

By:   
Oleg Iosadévich  
Reg. No. 56,963

Davidson, Davidson & Kappel, LLC  
485 Seventh Avenue, 14<sup>th</sup> Floor  
New York, New York 10018  
(212) 736-1940